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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0007]

HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is responding to comments on a Federal Register notice, "HACCP Plan Reassessment for Not-Ready-to-Eat (NRTE) Comminuted Poultry Products and Related Agency Verification Procedures," that it published on December 6, 2012. The notice provided updated information on the Agency's sampling and testing of these products, and on how it is verifying that establishments are effectively addressing the possible presence of Salmonella and Campylobacter in them.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development;

Telephone: (202) 205-0495 or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Background

In the December 6, 2012, Federal Register notice (77 FR

72686), FSIS informed establishments producing NRTE ground or otherwise comminuted chicken and turkey products that they must reassess their Hazard Analysis and Critical Control Point (HACCP) plans for these products. The Agency also described how it would determine whether the association of NRTE meat or poultry product with an illness outbreak would make subsequently-produced "like" product adulterated. FSIS announced that it would expand its Salmonella sampling beyond ground chicken and turkey to include all forms of non-breaded, non-battered comminuted NRTE chicken or turkey product not destined for further processing into ready-to-eat (RTE) products. Finally, FSIS announced that it intended to use the sampling results to determine the prevalence of Salmonella and Campylobacter in NRTE comminuted chicken and turkey and to develop pathogen reduction performance standards for these products.

In response to an industry request for more time to comment, on March 7, 2013, FSIS extended the original comment period for the December 2012 notice by 45 days, until April 20, 2013 (78 FR 14635). Also on March 7, 2013, FSIS stated in the notice that establishments that produced NRTE comminuted chicken or turkey products would have to reassess their HACCP plans for those products by April 20, 2013, thereby providing them an

additional 45 days to conduct the reassessment. Finally, FSIS announced that it would announce any new standards in the Federal Register and request comment on them before implementing them.

FSIS requested comment on the notice concerning the required reassessment and new sampling to inform FSIS's planned sampling procedures, to gather information on how best to establish pathogen reduction performance standards for NRTE comminuted chicken and turkey products, and to gather any other necessary information on how best to move forward with addressing Salmonella and Campylobacter in comminuted poultry products.

On May 8, 2013, FSIS issued instructions to its inspectors to begin verifying whether establishments had reassessed their HACCP plans (FSIS Notice 33-13; http://www.fsis.usda.gov/wps/wcm/connect/12ab8084-1641-4e9a-ba3c-c647afe7e428/33-13_447.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=12ab8084-1641-4e9a-ba3c-c647afe7e428). From the available data concerning establishment production and inspection task procedures from the Public Health Information System (PHIS) and from District Offices, FSIS found that about 70 percent of inspection personnel at establishments producing raw and not-heat-treated

NRTE ground or otherwise comminuted chicken or turkey product verified that the establishments had reassessed their HACCP plans for these products in light of the outbreak information provided in the December 2012 notice. Inspection personnel found that about 90 percent of the establishments at which verification occurred had complied with the reassessment requirements. Most of the establishments that had not reassessed were very low volume (less than 1,000 pounds average production of product subject to comminuted poultry sampling) and not included in the sampling frame for this product.

FSIS found that only 30 percent of inspection personnel verified whether establishments producing heat-treated NRTE comminuted chicken or turkey products had reassessed their HACCP plans for these products. Inspection personnel have had questions about whether reassessment is required for such products and have had questions concerning whether the poultry components of these heat-treated products have received a full lethality treatment or are comminuted. If the products themselves, or the comminuted poultry component of such products, receive a full lethality, they would not be subject to the HACCP plan reassessment requirement.

District Offices will work with inspection program personnel to ensure that they verify whether all establishments

required to reassess HACCP plans for NRTE comminuted (including ground) chicken or turkey product do so. In addition, FSIS intends to prioritize completion of Food Safety Assessments (FSAs) in establishments producing NRTE comminuted chicken or turkey product. During an FSA, if an Enforcement Investigations and Analysis Officer (EIAO) finds that an establishment producing such product has not reassessed its HACCP plan and should have done so, the EIAO will inform inspection program personnel at the establishment. Those personnel will then inform the establishment that it needs to reassess its HACCP plan for this product. If an establishment does not perform reassessment after it is advised to do so, FSIS will issue a noncompliance record. FSIS will post on its Website an update on what it finds on the status of reassessments through the poultry checklist, discussed below. In addition, FSIS will prepare and post a report on what it has learned about the reassessments from the FSAs that EIAOs have conducted.

FSIS began the new Agency sampling and testing of raw comminuted chicken and turkey products on June 1, 2013 (FSIS Notice 35-13; http://www.fsis.usda.gov/wps/wcm/connect/366615fa-923b-4d9a-954d-c6ad30ea3242/35-13.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=366615fa-923b-4d9a-954d-c6ad30ea3242). This sampling and testing for Salmonella and

Campylobacter does not include heat-treated NRTE comminuted chicken or turkey. FSIS is analyzing the results of the new sampling and testing. FSIS has posted aggregate results of this testing for all finished products as part of its quarterly report on Salmonella.¹

FSIS intends to continue the current sampling program until the new Salmonella and Campylobacter pathogen performance standards are implemented. FSIS intends to derive the new standards based on a risk assessment that takes into account the prevalence and distribution of Salmonella and Campylobacter in NRTE comminuted chicken and turkey product and the predicted illnesses averted as a consequence of reducing the prevalence of these pathogens. FSIS will estimate prevalence when it has collected enough data to develop standards.

Until FSIS establishes pathogen reduction performance standards for comminuted chicken and turkey, FSIS recommends that establishments increase their awareness of the pathogen incidence in these products and compare the on-going incidence in their establishments against the results made public by FSIS. In addition to the posted results, FSIS intends to provide each

¹ <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/quarterly-reports-salmonella/quarterly-progress-reports>.

establishment whose product the Agency samples with periodic status reports comparing that establishment's results with those industrywide. FSIS advises establishments to make necessary changes in their procedures to control Salmonella and Campylobacter, particularly if FSIS finds that the levels of these pathogens in their comminuted products are higher than those in similar products of most other establishments or higher than the standard.

If establishments implement pathogen control procedures and conduct their own verification testing, FSIS advises them to compare their results to FSIS results and to make necessary changes to control the pathogens if their results are higher than the results of FSIS's testing in most other establishments or the FSIS standard. As has been the Agency's practice since February 2006, when it first began encouraging establishments to gain more optimal and consistent process control by attaining Category 1 status (i.e., half the current number of acceptable positive samples in a sample set), FSIS continues to encourage establishments to gain more optimal and consistent process control by achieving test results that are better than those for most other establishments, and that are lower than the FSIS standard.

At this time, not all establishments apply antimicrobial

treatments to the source materials used for producing comminuted poultry, including mechanically separated product. FSIS is, therefore, revising its FSA Tools to ensure that EIAOs verify that establishments adequately address Salmonella and Campylobacter in comminuted poultry, including mechanically separated product, in their hazard analysis and food safety system.

Consistent with plans announced in the December 2012 Federal Register notice, FSIS is surveying its poultry inspection program personnel through a PHIS profile extension questionnaire during the first half of Fiscal Year (FY) 2014 to gather specific information on changes made to HACCP plans in response to the required reassessment (77 FR 72686, at 72689). FSIS will evaluate the information gathered from the questionnaires to determine what hazards the Agency needs to consider in establishments that produce NRTE comminuted chicken and turkey products, and that FSIS needs to target in industry-wide FSAs of comminuted poultry operations. Similarly, if any of the testing data show high numbers of Salmonella positives within an establishment, or high levels of Salmonella through enumeration, FSIS may conduct a for-cause FSA at the establishment that produced the product or increase verification testing or inspection procedures at the establishment, such as

sanitary dressing procedures, until the establishment controls pathogens on the source materials and food contact equipment. For slaughter operations, FSIS may slow down the evisceration line if conditions, including contamination resulting from a lack of process control, are preventing inspection personnel from adequately performing inspection procedures within the time available (9 CFR 381.68(c)).

FSIS announced its Salmonella Action Plan on December 4, 2013.² According to the plan, FSIS intends to complete a risk assessment and develop Salmonella performance standards for comminuted poultry this fiscal year. FSIS also intends to announce and request comment in the Federal Register on the setting of pathogen reduction performance standards for Salmonella and Campylobacter during this fiscal year for poultry parts and comminuted poultry. FSIS will then analyze the comments and announce final standards in a subsequent Federal Register notice and would provide time for establishments to make any changes to their procedures before assessing whether establishments meet the new standards. FSIS is analyzing the testing data discussed above to develop proposed new standards.

Summary of Comments and Responses

² <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/salmonella/sap>.

FSIS received 22 comments in response to the December 2012 notice. Of those comments, one was a joint submission signed by eight consumer advocacy groups, and another was from a coalition of six trade associations on behalf of their member companies. The remaining individual comments were from private citizens, domestic poultry processors, trade associations, industry advocacy associations, a consumer advocacy organization, a food marketing company, a private foreign consulting agency, and a member of academia. FSIS has summarized and responded to the comments below.

Administrative Procedure Act

Comment: One comment claimed that the Agency is violating the Administrative Procedure Act by effectively promulgating new regulatory requirements without following notice and comment procedures.

Response: The notice did not establish any new requirements. The December 2012 Federal Register notice was based on the Agency's determination that changes had occurred that could affect establishments' hazard analysis for comminuted poultry products because of the outbreaks and recalls described in the December 2012 notice. Therefore, as FSIS explained in the March 7, 2013 Federal Register, the predicate for triggering the reassessment required under 9 CFR 417.4 (a)(3) clearly existed

(78 FR 14635). FSIS provided recommendations on issues establishments should consider during the reassessment but did not require establishments to consider those specific issues.

Although FSIS did not set new requirements for industry, the Agency provided a comment period. In addition, before beginning new sampling or verifying that establishments had reassessed their HACCP plans, FSIS delayed implementation to carefully consider issues that were raised in comments.

Definition of NRTE Comminuted Poultry

Comment: Several comments commended FSIS for expanding its Salmonella verification sampling program to include previously untested forms of NRTE comminuted poultry products and for taking actions to assess the prevalence of Salmonella and Campylobacter in these products. However, a turkey processor remarked that the Agency's definition for NRTE comminuted poultry is "excessively broad." Instead of the term "comminuted," several comments stated that FSIS should maintain its current use of the terms "mechanically separated," as defined in 9 CFR Part 381, and "ground" when implementing the new sampling.

Response: FSIS considers "NRTE comminuted poultry" to be any NRTE chicken or turkey product that has been ground, mechanically separated, or hand- or mechanically deboned and

further chopped, flaked, minced or otherwise processed to reduce particle size (77 FR 72687). FSIS developed this definition to encompass not only ground and mechanically separated poultry products but also other similarly produced products across the spectrum of comminuted poultry products, including those with ingredients added during the comminution process, because production of any NRTE comminuted poultry involves similar processes that make them susceptible to the same hazards. FSIS had not previously included mechanically separated product or other comminuted product in its ground poultry sampling frame. By expanding the sampling frame to include all raw comminuted products, FSIS can verify that establishments are adequately controlling hazards in products produced by similar processes.

HACCP Plan Reassessment

Comment: Several comments supported HACCP plan reassessment for establishments producing NRTE comminuted chicken and turkey to take into account recent Salmonella outbreaks. Conversely, a domestic chicken processor and several trade associations objected to the required reassessment because FSIS failed to provide evidence in the notice that a food safety hazard has historically occurred or is reasonably likely to occur in the production of all NRTE comminuted poultry products. Several comments stated that the ground turkey products recalled

in 2011, discussed in the December 2012 notice, contained no mechanically separated turkey.

Response: Although one outbreak and a subsequent recall discussed in the December 2012 notice involved only ground turkey products, the 2011 Salmonella Heidelberg outbreak³ (FSIS Recall Case #060-2011)⁴ discussed in the notice was specifically associated with mechanically separated turkey source materials. Furthermore, all comminuted products undergo similar processing and, for that reason, are susceptible to the same hazards. Comminuting intact NRTE chicken or turkey spreads any surface contamination throughout the finished product. Thus, FSIS required reassessment of HACCP plans for all NRTE comminuted chicken and turkey products, including ground, hand- or mechanically-deboned, and mechanically separated product.

Importantly, on January 10, 2014, FSIS announced a product recall (FSIS Recall Case #001-2014) involving NRTE mechanically separated chicken, linked to an outbreak, that was sold for institutional use.

FSIS Salmonella Verification Sampling Program Procedures

Comment: One comment requested that FSIS exempt from

3 A total of 79 persons infected with the outbreak strain of *Salmonella* Heidelberg were reported from 26 states between March 1 and August 3, 2011.

4 Information on this recall and others can be found on the FSIS Web page (<http://www.fsis.usda.gov>), through the “FSIS Recalls” link, under the recall case number.

sampling and testing raw comminuted poultry and turkey source materials destined for High Pressure Processing (HPP). If the materials were not exempted from sampling and testing by FSIS, the commenter requested that establishments using HPP be granted the benefit of having product sampled in its final, packaged form, after the HPP Critical Control Point.

Response: Any chicken or turkey product treated with an intervention or antimicrobial treatment, including HPP, that has been validated to achieve at least a 7-log reduction of Salmonella in poultry product would be considered RTE and exempt from FSIS Salmonella verification sampling. (Raw meat product would need a 5-log reduction of Salmonella to be exempt from FSIS Salmonella testing.) The HACCP plan reassessment requirement announced in the December 2012 Federal Register notice did not apply to HACCP plans for RTE chicken or turkey products. FSIS generally attempts to sample product after the product has received all antimicrobial treatments. In the case of HPP, which oftentimes is applied off-site at another establishment, if controls are in place to ensure that the antimicrobial treatment is applied to the product, FSIS would attempt to sample product at the off-site locale after the antimicrobial treatment is applied.

Comment: An industry advocacy association stated that the

shifting to a 325-gram sample method will impair FSIS's and stakeholders' ability to compare historical and newly-generated data. The comment also requested that FSIS demonstrate how it validated a sampling methodology for poultry based on the larger sample size.

Response: FSIS agrees that comparing data generated before and after a microbiologic method change may be difficult. However, the 325-gram analytic portion will provide FSIS and industry with a more accurate estimate of the presence of Salmonella and Campylobacter in the products tested. The larger analytic portion size will also likely provide FSIS with a clearer picture of Salmonella serotype distribution. This increased understanding will assist FSIS with foodborne illness source attribution and outbreak traceback investigations.

To support an increase in the sample size analyzed, FSIS conducted studies to verify the performance characteristics (selectivity, sensitivity, reproducibility) of the FSIS Salmonella detection method (FSIS Microbiology Laboratory Guidebook Chapter 4.06) for poultry and found no significant difference between 25-gram and 325-gram analytical sample portions.

Comment: A trade association recommended that FSIS require safe handling and cooking instructions on all domestic and

exported NRTE comminuted poultry product labels. The commenter also recommended that FSIS require all mechanically separated poultry products to be processed into RTE products. Other commenters recommended that FSIS establish additional labeling requirements for NRTE comminuted products such as, "For Export Only," "Must Be Fully Cooked to a Temperature of 165°F (74°C)," "Not for Retail Sale," and stating the intended use of the product (NRTE or RTE) on the label.

Response: Safe handling instructions are required to appear on the labels of raw or partially cooked NRTE poultry products (9 CFR 381.125(b)). The remaining labeling and processing requirements suggested by the commenters would require rulemaking and are outside the scope of this notice. However, establishments can voluntarily include validated cooking instructions or statements of limited use on product labels.

This January, FSIS sought input from the National Advisory Committee on Meat and Poultry Inspection⁵ to explore possible changes to the safe food handling label on meat and poultry packages. With this input, FSIS will consider whether the current safe handling instruction requirements should be changed to meet the needs of the consuming public (78 FR 77643; Dec. 24,

⁵ For more information on the National Advisory Committee on Meat and Poultry Inspection, visit <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/advisory-committees/nacmpi..>

2013).

Estimating Prevalence

Comment: Several consumer advocacy organizations asked how the Agency intends to use its verification testing program to determine prevalence when, in April 2012, FSIS said it was not possible to estimate prevalence accurately by using its Salmonella verification data.

Response: To estimate prevalence in NRTE comminuted poultry products, FSIS has replaced its traditional sampling-set approach with a census-type approach where each establishment is sampled continuously. This change will allow estimation of the average prevalence in each establishment across the sampling period. In addition, post-hoc adjustments for production volume will allow for national Salmonella and Campylobacter prevalence estimation.

Comment: A consumer advocacy organization stated that, to get an accurate estimate of the national prevalence of Salmonella, FSIS must sample from all establishments producing NRTE comminuted poultry products, not just establishments in Category 3. Several comments recommended that the new sampling of comminuted chicken and turkey span at least one year to account for seasonality when estimating prevalence. An industry advocacy organization stated that this sampling program must

have enough samples taken across the seasons to be statistically significant.

Response: To estimate prevalence, FSIS is sampling eligible NRTE comminuted poultry product from all establishments producing it, regardless of category status. As stated above, FSIS is now analyzing the results of the new sampling and testing.

To address comments received on seasonality, FSIS analyzed Salmonella verification sampling data from 2000-2010 and found no significant seasonal patterns for either ground chicken or ground turkey. Accordingly, FSIS disagrees that the exploratory sampling period must span at least one year to account for seasonality. Furthermore, the existing pathogen reduction performance standards from the mid-1990s for both ground chicken and ground turkey are based on prevalence data collected over a period of approximately three to four months.⁶ However, FSIS will use at least 6 months of data on comminuted chicken and turkey to assess prevalence and developing standards.

New Performance Standards

Comment: Many comments requested separate performance

⁶ <http://www.fsis.usda.gov/OPHS/baseline/rwgrchck.pdf> and <http://www.fsis.usda.gov/OPHS/baseline/rwgrturk.pdf>, respectively.

standards for NRTE mechanically separated versus ground products because of the differences in how each product category is produced, marketed, and used. An industry advocacy association stated that a performance standard is not necessary for mechanically separated chicken products because mechanically separated chicken is only sold for inclusion in items that are fully cooked before sale to consumers.

Response: FSIS will develop separate Salmonella (and possibly Campylobacter) pathogen reduction performance standards for both chicken and turkey. Before determining whether to develop different pathogen reduction performance standards for different categories of NRTE comminuted poultry product, FSIS must consider the prevalence data for these categories that will be generated during its sampling program. If the data support doing so, FSIS may develop separate pathogen reduction performance standards for mechanically separated chicken and turkey. Although FSIS agrees that products that contain mechanically separated turkey now, after the August 3, 2011, recall, are typically sold to consumers fully-cooked, FSIS is aware of multiple establishments that produce NRTE products that contain mechanically separated chicken destined for sale to consumers as raw product. As noted earlier, the early January 2014 recall of mechanically separated chicken was marketed as

NRTE for institutional use and was associated with numerous illnesses. Importantly, FSIS is aware that both mechanically separated turkey and mechanically separated chicken are marketed for export as NRTE product. FSIS is working with the poultry industry to better ensure that this type of product is produced under control programs that ensure consistent pathogen reduction in the product.

Comment: A consumer advocacy organization suggested that FSIS set a performance standard that is no greater than 12.3 percent for NRTE comminuted turkey products to reflect recent National Antimicrobial Resistance Monitoring System (NARMS) data. A domestic processor requested that the new performance standard be rolled out over two years to allow for modifications in sampling methodologies.

Response: FSIS will base its estimate of the prevalence of Salmonella and Campylobacter in NRTE comminuted poultry products on the data collected during the sampling program, while considering other relevant data sources, including NARMS. As noted above, FSIS will announce any new pathogen reduction performance standards in the Federal Register and request comment on them before finalizing. In addition, before implementing the standards, FSIS will provide establishments with sufficient time to make any necessary changes to address the standards.

Adulterated Product

Comment: Several consumer advocacy organizations asked FSIS to declare specific strains of Salmonella adulterants. They noted the Agency's recent determination that certain strains of pathogenic Escherichia coli (E. coli) are adulterants. Another comment stated that FSIS should declare as an adulterant any Salmonella serotype that appears on the Center for Disease Control's "top 20" list of Salmonella serotypes of human health concern at <http://www.cdc.gov/ncezid/dfwed/PDFs/SalmonellaAnnualTable2009.pdf> and that is also antibiotic resistant.

Response: FSIS is considering a petition for rulemaking submitted by the Center for Science in the Public Interest (CSPI) requesting that the Agency issue an interpretive rule declaring certain antibiotic-resistant strains of Salmonella to be adulterants when found in ground meat and ground poultry.⁷ FSIS will address the issues raised by these commenters when we respond to the CSPI petition.

Comment: A consumer advocacy organization said that the Agency should declare as adulterated any raw product with the same pulsed field gel electrophoresis (PFGE) pattern as the

⁷ Available at http://www.fsis.usda.gov/wps/wcm/connect/04cb5fad-c13e-4de7-b391-2acd95191a95/Petition_CSPI_052511.pdf?MOD=AJPERES.

Salmonella serotype associated with an illness outbreak, even if the product was produced in an establishment that has no relationship to the product involved in an illness outbreak. Conversely, an industry advocacy organization remarked that deeming certain strains of Salmonella adulterated when linked to an illness would penalize establishments for events beyond their control.

Response: As is explained in the December 2012 Federal Register notice, FSIS would likely not consider product of the same type adulterated though it is found to have the pathogen associated with the illness outbreak if the product were produced in other establishments that have no relationship to product involved in the illness outbreak (77 FR 72686, at 72689). A determination of adulteration would be specific to the product linked to the illness outbreak, to the conditions in the establishment where that product was produced, and possibly to product in other establishments when there is a relationship to the product involved in the outbreak.

Exporting NRTE Comminuted Poultry Products

Comment: Several comments questioned the Agency's sampling eligibility policies for exported NRTE products outlined in FSIS

Notice 23-13.⁸ A foreign consulting firm and several domestic processors and trade associations argued that NRTE comminuted poultry product being exported for further processing into RTE product should be treated the same way as NRTE comminuted poultry product destined for processing into RTE product within official establishments in the United States. Therefore, these commenters stated, the product destined for export should be exempt from FSIS sampling and testing. Multiple trade associations asserted that the ability to export NRTE comminuted poultry should be based on the requirements of the importing country, not domestic requirements.

Response: FSIS stated in the Federal Register (73 FR 4767; Jan. 28, 2008) that it will exclude from the Salmonella verification testing program any establishment that diverts all of its raw products to another official, federally inspected establishment for further processing into a RTE product. The instructions provided to inspection personnel in FSIS Notice 23-13 are consistent with what we announced in the January 2008 Federal Register.

If an establishment sends NRTE mechanically separated poultry product to export, FSIS cannot verify that all of the

⁸ Available at http://www.fsis.usda.gov/wps/wcm/connect/d27b07b5-f3e0-4ae1-8aff-9390c57ce132/23-13_422.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=d27b07b5-f3e0-4ae1-8aff-9390c57ce132.

product exported will be processed into RTE product. Thus, if the product to be exported is in a class of product that FSIS samples and tests for Salmonella and Campylobacter, that product would be subject to FSIS verification sampling. In any case, even if the product is subject to FSIS Salmonella and Campylobacter testing, products otherwise eligible for export could still be exported. Such product needs to be produced under good manufacturing practices (GMPs) to ensure wholesomeness of the product. GMPs would include process controls to ensure pathogen reduction at least on the source materials, and on-going verification testing to demonstrate that the product is maintained in a wholesome manner. As is discussed above, FSIS is providing test results to industry on the distribution of contamination in this type of product. Establishments desiring to export such NRTE product should strive to consistently produce product with a pathogen positive rate below the industry average and the FSIS standard, if one exists.

If a foreign country notifies FSIS that it will accept raw product from the United States that is normally subject to Salmonella and Campylobacter sampling and testing, but only if the product is labeled "for cooking only" or with another statement that indicates that product is to be handled a certain way in that country, FSIS would include that new labeling

requirement in the export library. FSIS would need to approve the special claims on the labeling. In addition, inspectors would need to verify that the product meets the requirements in the export library, and that the product is going to a country that accepts the product as long as it bears the required labeling. If inspectors can verify these facts, FSIS likely would not sample and test the product for Salmonella and Campylobacter. However, if there is evidence that the establishment does not have adequate on-going controls to demonstrate that the product is maintained in a wholesome manner, FSIS may conduct intensified verification activities at this establishment, including testing and inspection procedures such as verification that the establishment maintains adequate sanitary dressing procedures, and that the establishment is effectively addressing pathogens. If FSIS is unable to verify that the establishment is addressing microbial contamination, FSIS may not certify the product for export.

Economic Impact of the Notice

Comment: One comment asserted that FSIS failed to address the negative economic impact of the 2012 Federal Register notice on the domestic poultry industry. An industry advocacy association estimated that it will cost some turkey producers close to \$100,000 to transition to the 325-gram analytic sample

size.

Response: As is explained above, FSIS's regulations require reassessment of HACCP plans when changes occur that could affect the HACCP plan or hazard analysis. Therefore, any costs associated with reassessment would not be "new" costs. Similarly, FSIS did not impose any new sampling requirements on establishments. If establishments choose to analyze their products for Salmonella or Campylobacter, they are not required to use the same sample analysis procedures as FSIS. The regulations require the establishment to maintain documents that support its verification activities and their frequency as appropriate for their intended purpose (9 CFR 417.5(a)(3)).

Comment: Several trade associations asserted that the changes announced in the notice will negatively affect exporters of NRTE mechanically separated poultry products⁹ because they will be unable to obtain export certificates for the products.

Response: FSIS finds no evidence that the notice will jeopardize the ability of exporters to obtain export certificates. Establishments can continue to export comminuted product even if it subject to FSIS testing.

Salmonella Control Strategies for Industry

⁹ Dr. Paul Aho, *Economic Impact of the Loss of the Export Market for Mechanically Separated Poultry Meat* (February 2013)

Comment: Several trade associations requested that FSIS provide small and very small establishments with specific guidance that will assist them in reassessing their HACCP plans for NRTE comminuted poultry and meat products.

Response: Guidance on how establishments can meet FSIS expectations (including pre-harvest and post-harvest suggestions) for the control of Salmonella and Campylobacter in poultry can be found in the Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry, Third Edition, May 2010.¹⁰

In addition, Attachment 1¹¹ to FSIS Notice 17-13¹² details lessons learned regarding establishment sanitation, intervention use, and cooking instructions validation associated with two outbreaks involving NRTE comminuted poultry products. FSIS also sent Historical Salmonella Serotype Information (HSSI) letters to establishments that produce raw comminuted chicken or turkey products and that have had ground poultry samples collected between January 2005 and January 2012. Together with any existing Salmonella End of Set Letters (EOSL), the HSSI letters and associated spreadsheets provide each establishment with

¹⁰ Available at

http://www.fsis.usda.gov/PDF/Compliance_Guide_Controling_Salmonella_Campylobacter_Poultry_0510.pdf.

¹¹ Available at <http://www.fsis.usda.gov/wps/wcm/connect/91c2976b-8eb4-4a7f-8390-9f7889f24709/NRTE-Comminuted-Turkey-Prod-Outbreaks.pdf?MOD=AJPERES>

¹² Available at http://www.fsis.usda.gov/wps/wcm/connect/f1e5822e-dd07-49d1-8bf7-ecd8d345c09a/17-13_412.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=f1e5822e-dd07-49d1-8bf7-ecd8d345c09a.

compiled serotype information on all available positive FSIS Salmonella results.

FSIS provided the information in the Attachment and in the HSSI letters because FSIS anticipated that establishments producing NRTE comminuted poultry products would find the information useful when they reassessed their HACCP plans for these products.

Comment: Multiple comments stated that FSIS failed to include in the December 2012 notice information on meaningful anti-Salmonella interventions or other factors that affect Salmonella control. Specifically, an industry advocacy organization stated that it is not practical to test for pathogens in incoming flocks, that pre-harvest information provides little useful information to set interventions, and that focusing on serotype-specific interventions is an ineffective approach to food safety. A member of academia said that insufficient attention is being paid to the practices of poultry growing operations.

Response: Establishments are in the best position to assess intervention use, including antimicrobial treatments, based on their knowledge of their own processes. However, as FSIS explained in the 2012 Federal Register notice, establishments should ensure that their slaughter and dressing procedures are

designed to prevent contamination to the maximum extent possible (77 FR 72686, at 72688). These procedures should, at a minimum, be designed to limit the exterior contamination of birds before exsanguination, as well as to minimize digestive tract content spillage during the dressing process. In addition, the Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry and Attachment 1 of FSIS Notice 17-13 provide guidance on the multiple-hurdle approach to reducing pathogens.

Establishments should identify the critical operating parameters of their antimicrobial interventions, as prescribed in their scientific support, and ensure that they are meeting these parameters effectively. FSIS found that the establishments associated with the outbreaks described in the December 2012 Federal Register notice were not consistently identifying the appropriate critical operating parameters of their antimicrobial interventions or consistently applying these interventions effectively against pathogens of concern. Inappropriate application of antimicrobial interventions can result in establishments not being able to reduce pathogens to acceptable levels.

FSIS considers serotype information to be useful because establishments may consider measures to control serotypes of

human health concern as well as measures to control all Salmonella. FSIS provides serotype information to assist establishments in identifying pathogen trends that may indicate one or more specific sources of Salmonella that establishments can address. Interventions may include serotype-specific interventions or controls that generally impact Salmonella in poultry.

Finally, FSIS encourages establishments, in considering food safety hazards that can occur before, during, and after entry into establishments, to consider pre-harvest factors that influence pathogens on incoming birds. The Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry¹³ includes pre-harvest information.

USDA Nondiscrimination Statement

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Persons with disabilities who require alternative means for

¹³ Available at http://www.fsis.usda.gov/wps/wcm/connect/6732c082-af40-415e-9b57-90533ea4c252/Compliance_Guide_Controling_Salmonella_Campylobacter_Poultry_0510.pdf?MOD=AJPERES.

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Done at Washington, DC on: April 15, 2014.

Alfred V. Almanza,

Administrator.

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